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(71) Applicant (for all designated States except US): SMITH & NEPHEW PLC [GB/GB]; 2 Temple Place, Victoria Embankment, London WC2R 3BP (GB).		Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	
(72) Inventor; and (75) Inventor/Applicant (for US only): PENROSE, Jane, Edith [GB/GB]; 45 The Close, Carleton Road, Skipton, North Yorkshire BD23 2BZ (GB).			
(74) Agent: SMITH & NEPHEW GROUP RESEARCH CENTRE; Corporate Patents & Trade Marks Dept., York Science Park, Heslington, York YO1 5DF (GB).			

(54) Title: UNDERCAST PADDING



(57) Abstract

Padding for use under rigid orthopaedic casts, comprising a polymeric foam net. The polymeric foam net comprises a first (2) and second (3) layer of substantially parallel filaments where the first layer is angled with respect to the second layer. The padding may further comprise an elastomeric lining layer (5).

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UNDERCAST PADDING

This invention relates to a novel form of padding for use under rigid casts used in the repair of for example bone fractures and
5 methods for their manufacture.

Padding materials for placing beneath an orthopaedic casting usually comprise soft conformable materials such as natural or synthetic non-woven materials, for example those sold by Smith &
10 Nephew Medical in the UK under the name SOFFBAN™.

However, such materials suffer from the disadvantage that they are generally unsuitable for use with water hardenable resin orthopaedic casts. Moreover, an advantage of using such resin
15 casts is that once such casts are set they can be brought into contact with water without any deterioration occurring, thus giving the patient much more freedom to carry on a normal life. However, since the underpadding absorbs water and generally suffers damage to its structure when in contact with water this limits the
20 patient's freedom. Moreover the presence of damp or wet undercast padding increases discomfort levels and the possibility of skin irritations and infections.

Other materials have been tried to provide an undercast
25 padding material which will not absorb moisture, such as a closed cell foam padding material in US Patent 4,294,240 where the material is slit so that when the material is stretched and wrapped around the body, some porosity is provided. US patent 4,516,572 provides a closed cell foam padding material, where the material is
30 made porous by a number of perforations.

Both the slits and perforations as described above are relatively widely spaced apart. However even when the closed cell foam padding material is stretched on application there is a relatively large amount of material in contact with the body surface.

- 5 In addition when the material is wrapped around the body any overlap of the material may result in a reduction of porosity.

- Thus it would be beneficial to provide a conformable, extensible padding, wherein large open areas are provided for improved water loss. Ideally a padding is provided that is porous for the transmission of water vapour for example from perspiration and water added for example during cast application or activities such as swimming.

- 15 A solution would be to provide underpadding in the form of a net, where preferably the net is made of layers. Each layer is made up of an array of substantially parallel filaments, where the layers are angled with respect to each other. An advantage of such an approach is that only the body facing layer of filaments may be in contact with the body, and thus the relative surface area of the net in direct contact with the body portion is small. The use of such a net allows the preparation of a thicker underpadding with more open spaces and with less material.

- 25 In addition it is advantageous if the undercast padding can be applied in one step, i.e. is a sleeve. Thus, it is desirable to provide a waterproof undercast padding which is sufficiently extensible to fit over a limb extremity, sufficiently resilient to provide padding around the limb and sufficiently smooth to allow it to slide over the surface of the limb.
- 30

According to the invention we provide an orthopaedic underpadding material comprising a polymeric foam net layer, characterised in that said polymeric foam net comprises a plurality of filaments.

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The polymeric foam net itself preferably comprises a first and second layer of polymeric filaments wherein the first layer comprising an array of substantially parallel filaments is angled with respect to the second layer comprising an array of substantially parallel filaments. The filaments of the first and second layer are connected at connection points such that one filament may move relative to the connected filament. The filaments of the first and second layer are connected such that any one first layer filament will be connected to a plurality of second layer filaments. Thus in the rest position the filaments will substantially overlay each other whereas in the expanded position, a net structure is achieved.

The first and second filament layers may be adhesively connected or may be connected by "spot welding" a thermoplastic filament or the connection may be formed by the curing of the filaments which may cause the filaments to bond to one another. However, the filaments must be connected such that one filament may be able to move, e.g. rotate about the bond, relative to the connected filament.

25

The size of the net mesh will vary according to the positioning of the connections between the first and second layers. Thus in an embodiment of the present invention the connection points between the filament layers are at least 0.2cm apart. Preferably the connection points may be spaced every 0.2 to 4.0cm.

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Any conventional polymeric material may be used. Closed cell foams are preferred, also preferred are foams which possess elastomeric properties. Hydrophilic or hydrophobic foams, but generally hydrophobic foams are preferred. Foams with thermal insulation properties are preferred. It is within the scope of this invention to include profiled or reticulated foams. The foam may be elastomeric or non-elastomeric although it is preferable for the foam to have some elastic properties, i.e. to be slightly stretchable. Preferably such foams substantially comprise polyalkylenes, for example polypropylene or polyethylene or polymers comprising mixtures of polyalkylenes. In a particularly preferred embodiment of the invention the polymeric foam net is made of a polyalkylene composition comprising a mixture of polyethylene, polypropylene and "Master Batch" (comprising 25% metal carbonate and 75% low density polyethylene), for example, the following composition is preferred;

	78% low density polyethylene
	8% polypropylene
20	14% "Master Batch"

When used as an orthopaedic underpadding material the polymeric foam net is to provide padding, and depending on the method of manufacture, for example by extrusion as hereinafter described, the foam filaments may be substantially cylindrical, and preferably have a have a thickness of at least 0.5mm and more preferably from 0.5mm to 15.0mm.

To further increase comfort levels for the patient further layers may be provided. The further layers may be linings on either side, or on both sides of the polymeric foam net. The linings may comprise polymeric foam nets, for example with a different mesh sizes. The

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use of a smaller mesh size would provide the wearer with additional protection from the casting resin and dust generated during removal of the casts. Other materials include knitted or woven fabrics, stockinettes or a non absorbent liner. Suitable stockinettes can
5 comprise hydrophilic or hydrophobic fibres or mixtures comprising both such fibres. Hydrophobic fibres such as nylon are preferred.

In an embodiment of the present invention at least a second lining layer is provided. Preferably the lining layer is an elastomeric
10 lining layer, therefore in a most preferred embodiment an elastomeric second lining layer is provided. Thus the two layers comprise an underpadding composite. Preferably the elastomeric second lining layer is made of a smooth material which dries out quickly and an example of such an elastomeric layer is a stockinette
15 sold by Smith & Nephew Medical in the UK under the name of TENSOGRIPTM.

According to the invention we provide a composite orthopaedic underpadding material comprising a polymeric foam net layer and
20 an elastomeric second lining layer.

The orthopaedic underpadding material of the invention may be constructed in a number of forms, including a sheet, a long strip such a bandage and a sleeve. Herein a sleeve is defined as
25 having a tubular form. Thus in a preferred embodiment of the invention the polymeric foam net is provided as a sleeve.

In a further embodiment of the invention, wherein a composite underpadding material is provided as a sleeve, a smooth
30 elastomeric second lining layer forms the inner layer of the sleeve and the polymeric foam net layer forms the outer layer of the sleeve.

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It is a particular advantage of the present invention to provide an orthopaedic undercast padding material which is a sleeve.

The inner layer can be a fabric such as knitted stockinette or a
5 woven or non-woven fabric sleeve which has been rendered elastically extensible as hereinafter explained.

The elastic component or components in an elastic sleeve of the invention can conveniently extend in a circular or helical fashion
10 around the circumference of the sleeve.

The outer and inner layers can suitably be attached by any conventional method including heat or adhesive bonding or by a mechanical method such as stitching.

15

In use, the outer layer of the orthopaedic underpadding material may overlay the inner layer, i.e. without being bonded together. However, the inner and outer layers of the orthopaedic underpadding material of the invention may be adhered to each
20 other by a layer of adhesive, for example a moisture vapour permeable adhesive. The adhesive may be a hot melt or pressure sensitive adhesive.

The outer and inner layers can be heat bonded by means of a
25 hot melt adhesive or interposed heat meltable layer.

The polymeric foam net may also be provided with a cohesive coating. This is particularly suitable if the polymeric foam net is provided as a sheet or bandage, and allows the net to be easily held
30 in place before the application of a cast. Alternatively a polymeric foam net sleeve may be provided with a cohesive coating to prevent the sleeve from slipping or rucking and thus increases comfort for

the wearer. Preferably the cohesive coating is a latex coating. Most preferably, the latex coating is provided only on the elastomeric layer facing side of the polymeric foam net.

- 5 The latex is usually coated onto the material at a density of 5 to 20gm^{-2} for each side of the material, preferably 5 to 15gm^{-2} and especially 8 to 15gm^{-2} .

- 10 The invention may be provided in kit form such that a medical practitioner may first apply an elastomeric lining layer to a patient followed by an application of the polymeric foam net layer of the invention.

- 15 The kit comprises at least two components, wherein the first component consists of the polymeric foam net of the invention and an elastomeric lining layer. A third component may comprise a hardenable casting material. Preferably the components are provided as sleeves. In a further embodiment the sleeves are provided as a single composite sleeve where the layers overlay one
20 another. In yet another embodiment some or all of the components, for example in the form as sleeves, sheets or bandages may be connected as hereinbefore described.

- 25 The undercast padding material provided in the kit may comprise a composite padding material or may comprise a smooth elastomeric material and a polymeric foam net as separate components.

- 30 In a most preferred embodiment the kit comprises a composite sleeve, comprising at least two components, wherein a first component consists of a plurality of filaments in the form of a

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polymeric foam net and a second component of an elastomeric lining layer.

According to the invention we provide a further kit comprising
5 an undercast padding material as hereinbefore described and an orthopaedic casting tape, for example a resin coating casting tape such as a water hardenable resin coated casting tape.

According to the invention we provide a method of treatment of
10 a fracture of a body portion which comprises applying a layer of the polymeric foam net according to the invention followed by applying a hardenable casting material.

According to the invention we further provide a method of
15 treatment of a fracture of a body portion which comprises applying a smooth, elastomeric lining layer to the body portion, overlaying with a layer of the polymeric foam net according to the invention followed by applying a hardenable casting material.

20 In a further aspect of the invention we provide a method of treatment of a fracture of a body portion, which comprises applying a composite sleeve consisting of a polymeric foam net and an elastomeric second lining layer to the body portion, followed by applying a hardenable casting material.

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The method is particularly advantageous in that where the casting material is a water hardenable material, for example a resin, the body portion dressed in the underpadding and the hardenable casting material may be immersed in water without reducing the
30 efficiency of the padding. Thus we provide a method of treatment as hereinbefore described wherein the body portion is immersed in water.

The underpadding material as herein before described may be manufactured using conventional methods known *per se*. For example, polymeric foam filaments may be extruded onto a rotating
5 drum and foamed by expansion using an inert gas. Composite orthopaedic underpadding materials may be manufactured by stretching a stockinette over a mandrel and extruding polymeric foam filaments onto the stockinette.

10 The invention will now be described, but in no way limited by reference to the accompanying drawing in which Figure 1 is a schematic cross-sectional view of the composite underpadding material;

Figure 2 is a schematic representation of an undercast
15 padding polymeric foam net in the rest position; and

Figure 3 is a schematic representation of an undercast padding polymeric foam net in the expanded position.

With reference to Figure 1, the composite orthopaedic
20 underpadding material comprises a polymeric foam net, consisting of a first layer of polymeric foam filaments (2) and a second layer of polymeric foam filaments (3) and further a smooth elastomeric second lining layer (5),

25 With reference to Figure 2, the undercast padding material (1) comprises a polymeric foam net, consisting of a first layer of polymeric foam filaments (2) and a second layer of polymeric foam filaments (3) bonded to one another at interstices (4).

30 In Figure 3 the polymeric foam net consisting of polymeric foam filaments (2 and 3) is shown in expanded form, where the first

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and second layer of polymeric foam filaments (2 and 3) are bonded to one another at interstices (4).

5 In use the smooth elastomeric second lining layer, for example a stockinette will be placed over a patient's limb and a polymeric foam net layer, for example a foam net sleeve, will be placed on the outer facing surface of the stockinette. A resin coated or resin impregnated casting tape may then be wrapped around the underpadding material and the resin is then cured to produce a hard
10 cast.

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CLAIMS

1. An orthopaedic underpadding material comprising a
polymeric foam net layer, characterised in that said polymeric foam
5 net comprises a plurality of filaments.
2. An orthopaedic underpadding material as claimed in claim 1,
characterised in that said polymeric foam net itself comprises a first
and second layer of polymeric filaments, wherein
10 a) the first layer comprising an array of substantially parallel
filaments is angled with respect to the second layer comprising an
array of substantially parallel filaments, and
b) the filaments of the first and second layer are connected at
connection points such that one filament may move relative to the
15 connected filament.
3. An orthopaedic underpadding material as claimed in claim 1,
wherein said filaments have a thickness of at least 0.5mm.
- 20 4. An orthopaedic underpadding material as claimed in claim 2,
characterised in that the connection points between said filaments
are at least 0.2cm apart.
5. An orthopaedic underpadding material as claimed in claim 1,
25 characterised in that said polymeric foam net is provided as a
sleeve.
6. An orthopaedic underpadding material according to claim 1,
characterised in that at least a second lining layer is provided.
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7. An orthopaedic underpadding material according to claim 6, characterised in that an elastomeric second lining layer is provided.

8. An orthopaedic underpadding material according to claim 1,
5 characterised in that said polymeric foam net is provided with a cohesive coating.

9. An orthopaedic underpadding material as claimed in claim 8, characterised in that said cohesive coating is latex.

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10. An orthopaedic underpadding material as claimed in claim 8, characterised in that said cohesive coating is on the elastomeric layer facing side of the polymeric foam net.

11. An orthopaedic underpadding material as claimed in claim 1, characterised in that said polymeric foam net substantially comprises polyalkylenes.

12. An orthopaedic underpadding material as claimed in claim
20 11, characterised in that said polyalkylene comprises a mixture of polyethylene, polypropylene and Master Batch.

13. Use of a polymeric foam net as claimed in claim 1, in the manufacture of an orthopaedic undercast padding.

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14. A kit comprising at least two components characterised in that a first component consists of a plurality of filaments in the form of a polymeric foam net and a second component of an elastomeric layer.

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15. A kit according to claim 14 characterised in that said components are provided as sleeves.

16. A kit according to claim 14 comprising a third component of a hardenable casting material.

5 17. A kit according to claim 14, characterised in that said components are provided as a composite.

18. A kit according to claim 17, characterised in that said composite is provided as a sleeve.

10

19. A process for the manufacture of an orthopaedic undercast padding as claimed in claim 1, characterised in that polymeric foam filaments are extruded onto a rotating drum.

15 20. A process for the manufacture of an orthopaedic undercast padding as claimed in claim 1, characterised in that polymeric foam filaments are extruded onto an elastomeric layer stretched onto a rotating drum.

20 21. A method of treatment of a fracture of a body portion which comprises applying a layer of polymeric foam net as claimed in claim 1 to said body portion followed by applying a hardenable casting material.

25 22. A method of treatment of a fracture of a body portion which comprises applying an elastomeric second lining layer to the body portion and overlaying with a polymeric foam net layer as claimed in claim 1 to said body portion followed by applying a hardenable casting material.

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FIG. 1.

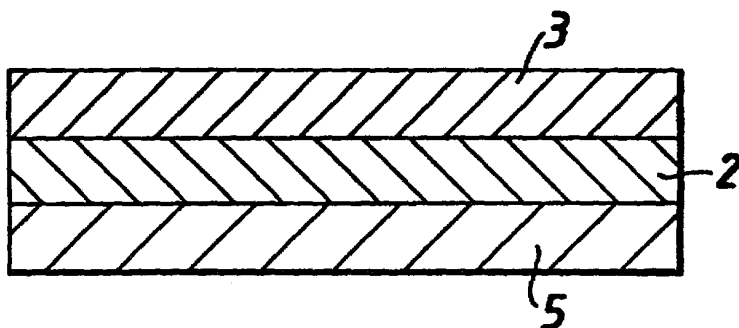


FIG. 2.

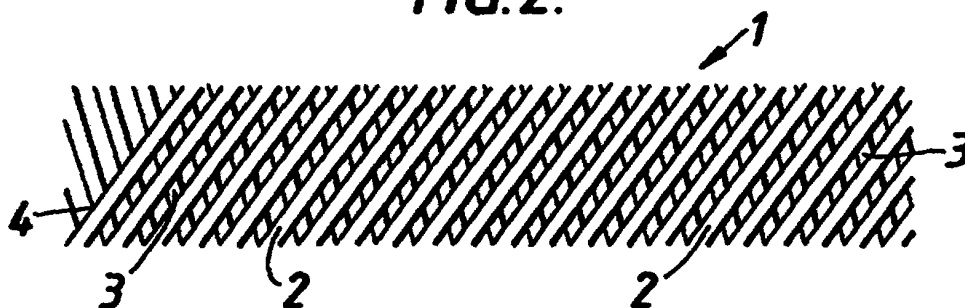
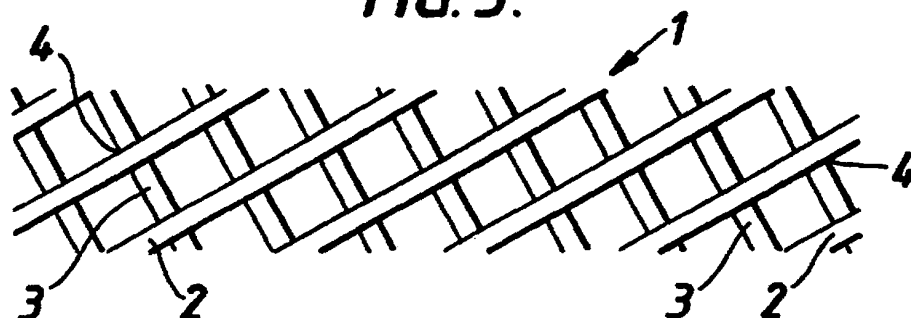


FIG. 3.



INTERNATIONAL SEARCH REPORT

International Application No

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61F13/04

According to International Patent Classification (IPC) or to both national classification and IPC

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Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US,A,4 294 240 (G.A.THILL) 13 October 1981 cited in the application see claim 1; figure 2 see column 2, line 53 - line 55 see column 3, line 18 - line 21 see column 3, line 50 - line 52 ---	1-5,8, 13,21
Y	US,A,3 862 878 (K.AZUMA) 28 January 1975 see column 4, line 64 - column 5, line 20; figures 3,10 ---	1-5,8, 13,21
A	US,A,4 660 553 (D.POCKNELL AND C.NAYLOR) 28 April 1987 see claims ----- -/-	1,21

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2220 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax (+31-70) 340-3016

Authorized officer

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